

SETTLEMENT AGREEMENT

This Settlement Agreement (“Agreement”) is made and entered into by and between the United States of America, acting through the United States Department of Justice and its Drug Enforcement Administration (“DEA”) (collectively, the “United States”), and The General Hospital Corporation, d/b/a Massachusetts General Hospital, and its sole member, The Massachusetts General Hospital (collectively, “MGH”) (together, the “Parties”).

Recitals

A. MGH is the largest hospital in Massachusetts, the largest teaching hospital of Harvard Medical School, and a biomedical research facility. It currently holds twelve active DEA registrations as set forth in Attachment 1 hereto.

B. Each DEA registrant is required to conduct its operations in accordance with the Controlled Substances Act, 21 U.S.C. § 801, *et seq.* (the “Act”), and the regulations promulgated thereunder.

C. The DEA is the Department of Justice component agency primarily responsible for enforcing the Act and is vested with the responsibility of investigating violations of the Act.

D. The United States Attorney General, through the United States Attorney’s Office, has primary authority to bring civil actions to enforce the Act. See 21 U.S.C. § 871 and 28 C.F.R. § 0.55(c).

E. The United States contends that, during the period from October 4, 2011, through April 1, 2015, MGH negligently failed to make, keep, or furnish certain records required to be kept under the Act, and failed to provide effective controls and procedures to guard against theft and loss of controlled substances. More specifically, the United States contends that it has civil

claims against MGH for engaging in the alleged conduct described in the United States’

Statement of Relevant Conduct set forth in Attachment 2 and as follows:

1. MGH failed to notify the DEA of nurse J.S.’s theft of controlled substances within one business day of discovery, in violation of 21 C.F.R. § 1301.76(b);
2. MGH failed to notify the DEA of nurse J.Z.’s theft of controlled substances within one business day of discovery, in violation of 21 C.F.R. § 1301.76(b);
3. MGH failed to provide effective controls and procedures to guard against theft and diversion of controlled substances, in violation of 21 C.F.R. § 1301.71;
4. MGH failed to maintain complete and accurate records of all controlled substances that it received, sold, delivered, or otherwise disposed of, in violation of 21 C.F.R. §§ 1304.21 and 1304.22(c);
5. MGH failed to document 358 transfers of Schedule II controlled substances using the required DEA Form 222, in violation of 21 C.F.R. § 1305.03;
6. MGH failed to document 407 transfers of Schedule IV controlled substances with invoices, in violation of 21 C.F.R. § 1304.22(b);
7. The MGH medical practice with DEA registration number xxxxxx349 failed to conduct an initial inventory, in violation of 21 C.F.R. § 1304.11(b);
8. The MGH medical practice with DEA registration number xxxxxx349 and the MGH pharmacy with DEA registration number xxxxxx423 failed to conduct biennial inventories, in violation of 21 C.F.R. § 1304.11(c);
9. MGH’s inpatient pharmacy conducted a biennial inventory that was incomplete, in violation of 21 C.F.R. § 1304.11(a) and (c); and

10. MGH failed to maintain current and accurate records of controlled substances in its automatic drug-dispensing machines (“ADMs”), in violation of 21 C.F.R. § 1304.22(a).

The conduct referred to in this Recital E and Attachment 2 is referred to below as the Covered Conduct.

In consideration of the mutual promises and obligations of this Agreement, the Parties agree and covenant as follows:

Terms of Agreement

1. No later than 10 days after the date on which this Agreement is signed by all Parties, MGH shall pay the United States Two Million, Three Hundred Thousand Dollars (\$2,300,000.00) (the “Settlement Amount”). The Settlement Amount shall be paid by electronic funds transfer pursuant to written instructions from the United States.
2. No later than 10 days after the date on which this Agreement is signed by all Parties, MGH and DEA will enter into the three-year Corrective Action Plan (“CAP”) that is Attachment 3 hereto.
3. In consideration of the obligations of MGH in this Agreement, conditioned upon MGH’s timely paying the Settlement Amount and entering into the CAP, and subject to the conditions in Paragraph 4, the United States releases MGH and Partners Healthcare System, Inc. (“Partners”), and their assigns, successors, principals, management, officers, directors, agents, and employees, from any civil or administrative claims the United States has, could have, or may assert in the future related to the Covered Conduct under the Act.
4. This Agreement in no way alters or restricts the United States’ right to enforce the Act and regulations promulgated thereunder by commencing a civil or administrative action

against MGH or Partners for any violations of the Act which are not based on the Covered Conduct, nor does it restrict the United States or any other sovereign or governmental entity from bringing any criminal charge against MGH, Partners, or any employee of either MGH or Partners. Also, this Agreement does not prevent any sovereign other than the United States from pursuing civil, criminal, and/or administrative claims against MGH or Partners for the Covered Conduct and/or any other conduct. However, this Agreement in no way waives MGH's or Partners' right to raise any defenses in any such actions.

5. MGH and Partners release the United States and its agencies, officers, agents, employees, and servants, from any claims (including for attorney's fees, costs, and expenses of every kind and however denominated) that MGH and/or Partners has asserted, could have asserted, or may assert in the future against the United States or its agencies, officers, agents, employees, or servants, related to the Covered Conduct and the United States' investigation and prosecution thereof.

6. The obligations imposed upon MGH pursuant to this Agreement and the CAP are in addition to, and not in derogation of, all requirements imposed upon MGH pursuant to all applicable federal, state, and local laws and regulations, including but not limited to the requirements set forth in Title 21 of the United States Code and the regulations promulgated thereunder.

7. Each party and signatory to this Agreement represents that it/he/she freely and voluntarily enters into this Agreement without any degree of duress or compulsion.

8. This Agreement is intended to be for the benefit of the Parties only; it does not create any rights or benefits as to third parties. The Parties do not release any claims against any other person or entity.

9. This Agreement is governed by the laws of the United States. The exclusive jurisdiction and venue for any dispute relating to this Agreement is the United States District Court for the District of Massachusetts. This Agreement shall be deemed to have been drafted by all Parties to this Agreement and shall not, therefore, be construed against any Party for that reason in any subsequent dispute.

10. This Agreement and the CAP constitute the complete agreement between the Parties. This Agreement may be amended only by a writing signed by all Parties.

11. The undersigned counsel represent and warrant that they are fully authorized to execute this Agreement on behalf of the Parties.

12. This Agreement may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same agreement.

13. This Agreement is binding on MGH's successors, transferees, and assigns.

14. Nothing in this Agreement constitutes an agreement by the United States concerning the characterization of the Settlement Amount for purposes of the Internal Revenue laws, Title 26 of the United States Code.

15. Each Party shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

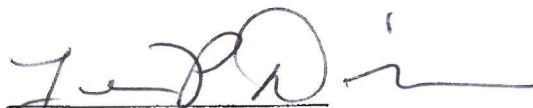
16. All parties consent to the United States' disclosure of this Agreement, and information about this Agreement, to the public, except that the names and contact information in paragraph 3 of Attachment 3 may be redacted and kept confidential.

17. The Parties may execute this Agreement via facsimile and/or by portable document format (.pdf), both of which shall be deemed the equivalent of an original signature.

18. This Agreement shall be effective on the date of signature of the last signatory to the Agreement ("Effective Date").


THE UNITED STATES OF AMERICA

DATED: 9/28/15

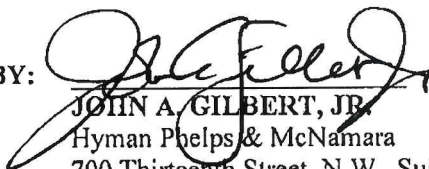
BY: 
JESSICA P. DRISCOLL
Assistant U.S. Attorney
United States Attorney's Office
District of Massachusetts

MASSACHUSETTS GENERAL HOSPITAL

DATED: 9/28/15

BY: 
TOBY R. UNGER
Partners HealthCare System
50 Staniford Street, 10th Floor
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DATED: 9/28/15

BY: 
JOHN A. GILBERT, JR.
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Attachment 1: MGH's Active DEA Registrations

DEA #	Address	City	Reg. Type
xxxxxxx433	55 Fruit Street	Boston	Hospital/Clinic
xxxxxxx926	55 Fruit Street	Boston	Hospital/Clinic
xxxxxxx423	55 Fruit Street	Boston	Research
xxxxxxx349	165 Cambridge Street	Boston	Hospital/Clinic
xxxxxxx242	32 Fruit Street	Boston	Analytical Lab
xxxxxxx293	73 High Street	Charlestown	Hospital/Clinic
xxxxxxx569	133 ORNAC	Concord	Hospital/Clinic
xxxxxxx755	40 Second Avenue	Waltham	Hospital/Clinic
xxxxxxx355	300 Ocean Avenue	Revere	Hospital/Clinic
xxxxxxx664	151 Everett Avenue	Chelsea	Hospital/Clinic
xxxxxxx288	102 Endicott Street	Danvers	Hospital/Clinic
xxxxxxx933	52 Second Avenue	Waltham	Hospital/Clinic

Attachment 2: United States' Statement of Relevant Conduct

The United States alleges that the following occurred during the period October 4, 2011, through April 1, 2015.

1. DEA began its investigation after learning that MGH nurse J.S. had stolen 14,492 pills from an automated drug-dispensing machine ("ADM"), and MGH nurse J.Z.1 had stolen 1,429 pills from a different ADM. Most of the pills they stole were oxycodone, a Schedule II drug. MGH did not discover J.S.'s actions until she had been stealing for an entire year – even though she sometimes appeared high to co-workers and other times was seen falling asleep at work. MGH failed to report these diversions to DEA within one business day as required by 21 C.F.R. § 1301.76(b).

2. In November-December 2013, DEA investigators conducted accountability audits of sample controlled substances in MGH's inpatient pharmacy and its outpatient pharmacy. The government alleges that the audits revealed 16,681 missing or extra pills at the inpatient pharmacy, and 7,177 missing or extra pills at the outpatient pharmacy. Most of the missing or extra pills were oxycodone, a Schedule II controlled substance.

3. The government alleges that MGH failed to provide effective controls and procedures to guard against theft and diversion of controlled substances, in violation of 21 C.F.R. § 1301.71. Many of these deficiencies concerned ADMs which MGH kept in locked medication rooms, operating rooms ("ORs"), and pharmacies. For example:

- a. During the period October 9, 2013, through December 31, 2013, MGH relied on a pharmacy information system ("PIS") to generate inventory figures for its ADMs in response to a request by DEA. However, the PIS data did not match the ADM data.
- b. During the period October 4, 2011, through May 2014, patient names remained active in the ADMs up to 72 hours post-discharge. This was one way that J.S. and J.Z.1 were able to divert drugs.
- c. On November 5, 2013, MGH documents listed one doctor, S.J., as having access to ADMs even though S.J. had left MGH four months earlier.
- d. On November 5, 2013, MGH documents listed another doctor, T.A., as having access to the ADMs even though T.A. had surrendered his medical license and his DEA registration in early 2013.
- e. Sometimes ADMs had inaccurate readings of dosage units. For example, during a DEA audit on October 31, 2013, one ADM showed that it contained 22 lorazepam 0.5 mg pills. However, DEA investigators found not only the 22 lorazepam 0.5 mg pills, but also another cartridge in the machine containing an additional 25 lorazepam pills that was not registering on the machine's computer.

- f. From October 4, 2011, through May 2014, MGH staff could access drugs in some ADMs for up to two minutes before lockout occurred. This extended time period before lockout allowed users to continue to access the machine and make multiple withdrawals.
- g. From October 4, 2011, through February 2014, the inpatient pharmacy staff were not alerted to medication overrides in ADMs. (A medication override occurs when a staff member enters his/her user ID and password into an ADM to get medication for a patient; the ADM displays a list of all patients in the unit and their medication orders; and the staff member selects either a higher dose than what is listed for the patient or a medication not on that patient's list.) Both nurses referenced in paragraph 1 above diverted drugs by using medication overrides.

4. The government alleges that certain members of MGH management demonstrated a supervisory failure to provide effective controls and procedures to guard against theft and diversion of controlled substances, in violation of 21 C.F.R. § 1301.71. For example:

- a. From October 4, 2011, through March 2014, many nursing supervisors failed to regularly review ADM reports to look for possible diversion, and some, including J.Z.1's supervisor, were not aware how often they were expected to review the reports. Failure to regularly review ADM reports enabled diversion by allowing medication overrides and "wrong bin opened" incidents to go undetected.
- b. When asked why MGH waited so long to implement controlled substance surveillance software, which produces user-friendly reports of ADM data indicating potential drug diversion, one MGH manager told the DEA that MGH is "rooted in tradition" and "change doesn't happen fast around here."
- c. MGH uses an anesthesia electronic health record ("EHR") to document the amounts of controlled substances administered in each OR. On occasions when the anesthesia EHR for a particular surgery did not match the drug kit reconciliation for that surgery, the OR pharmacy asked the medical personnel involved to address the discrepancy.
- d. A certified registered nurse anesthetist, A.S., lost small amounts of controlled substances three different times within eight months. She was not disciplined.
- e. Another certified registered nurse anesthetist, S.W., lost controlled substances four different times within eight months. She was not disciplined. S.W.'s supervisor told the DEA that she chose to have only an "offhand conversation" with S.W. about these incidents because S.W. was up for a promotion and she did not want to hurt S.W.'s chances.

5. The government alleges that MGH also failed to provide effective controls and procedures to guard against theft and diversion of controlled substances, in violation of 21 C.F.R. § 1301.71, as follows:

- a. From October 4, 2011, until December 2013, every OR at MGH contained an unlocked “Bluebell” cart in which medical staff stored their controlled substances when on break.
- b. During the period October 4, 2011, until November 1, 2012, some anesthesia residents who needed controlled substances for 9:30 am cases signed them out early and took them to off-campus grand rounds at 7:00 am. MGH did not discipline residents for this practice.
- c. On November 14, 2011, three syringes of hydromorphone, remifentanyl, and morphine were found in various ORs. No one knew where they came from or to whom they belonged.
- d. In November 2011, an MGH inpatient pharmacy manager reported 20 syringes of morphine were missing from the pharmacy vault during unit moves and renovations.
- e. An MGH physician, E.P., repeatedly prescribed controlled substances for patients without seeing them and without maintaining medical records, in 2012-2013. His patients included at least one who was simultaneously obtaining prescriptions for controlled substances from other physicians. E.P. voluntarily surrendered his DEA registration in 2014.
- f. From October 4, 2011, through December 2013, medical personnel often took controlled substances with them to lunch at the on-site hospital cafeteria as a matter of convenience.

6. The government alleges that, as a result of MGH’s failure to provide effective controls and procedures to guard against theft and diversion of controlled substances, in violation of 21 C.F.R. § 1301.71, theft and diversion occurred, and not just by J.S. and J.Z.1. For example:

- a. In May 2014, MGH discovered that nurse M.B. had been diverting controlled substances (oxycodone, Percocet, Dilaudid, Valium, Ativan, morphine, Flexeril, and Vicodin) from the emergency room for four years. MGH was unable to determine the amount she diverted.
- b. In May 2014, MGH discovered that nurse M.M. had diverted Dilaudid for seven years (2007-2010 and 2012-2014).
- c. In June 2014, MGH discovered 34 drug transaction discrepancies that nurse J.L. was unable to explain. The drugs at issue were Ativan, Dilaudid, fentanyl, ketamine, Valium, morphine, and Versed. The nurse denied

diverting the drugs and blamed the discrepancies on lack of documentation and the rushed pace in the emergency room.

- d. In August 2014, MGH discovered that R.C., a pediatric surgery nurse, had had a substance abuse issue off and on for the past twelve years. He was found sleeping at work, unsteady on his feet, and with slurred speech. He admitted diverting Dilaudid, a Schedule II drug, and injecting himself at work.
- e. In August 2014, MGH discovered that nurse J.Z.2 had repeatedly taken home controlled substances, allegedly by mistake, and provided no documentation of waste. (All controlled substances signed out must be used, returned, or wasted. In all cases, the amounts must be documented.)
- f. In December 2014, 42 vials of controlled substances were found in the apartment of a deceased MGH anesthesia resident, who was determined to have died of natural causes. Five of the vials contained MGH labels.
- g. In January 2015, nurse C.F. admitted to diverting various quantities of narcotic waste, including fentanyl, Versed and Demerol, at least 25 times in the past year.

7. The government acknowledges that, since the start of the DEA's diversion investigation in October 2013, MGH has taken significant steps to improve its controls and procedures against theft and diversion of controlled substances, including adoption of the Corrective Action Plan set forth in Attachment 3.

Attachment 3 - Corrective Action Plan

This Corrective Action Plan (“CAP”) between Massachusetts General Hospital (“MGH”) and the U.S. Drug Enforcement Administration (“DEA”) memorializes the policies and procedures that MGH and the DEA (jointly, the “Parties”) have agreed upon to advance MGH’s efforts to ensure compliance with the Controlled Substances Act (the “Act”) and to enhance MGH’s ability to prevent, detect, and address drug diversion.

1. This CAP is incorporated by reference at paragraph 2 of the Settlement Agreement between MGH and the United States dated September 28, 2015 (the “Settlement Agreement”).

2. The period of this CAP shall be three years, starting on the Effective Date of the Settlement Agreement.

3. Whenever this CAP requires notice to the DEA, the persons to be notified will be [REDACTED] and [REDACTED]. Whenever this CAP requires notice to MGH, the person to be notified will be [REDACTED]. Either party may change the name and/or contact information of its contact person(s) by so notifying the other party’s contact person(s).

4. MGH represents that it began to implement certain diversion controls (“Enhanced Controls”) following the commencement of the DEA’s diversion investigation in October 2013. MGH agrees to promptly complete implementation of the Enhanced Controls at all twelve of its current DEA registrations (as identified on Attachment 1 to the Settlement Agreement), and at every facility that receives a DEA registration during the term of this CAP. The Enhanced Controls include the following:

- a. Employing a full-time Drug Diversion Compliance Officer.
- b. Establishing a drug diversion team consisting of the Drug Diversion Compliance Officer; members of the compliance, pharmacy, and nursing departments; and MGH Police & Security. The drug diversion team is tasked with preventing, monitoring, and responding to incidents of drug diversion.
- c. Conducting mandatory annual training for all staff with authorized access to controlled substances, including training on the signs and symptoms of substance abuse and addiction, drug diversion monitoring and prevention, the duty to report, and the filing of safety reports.
- d. Purchasing controlled substance surveillance software, which produces user-friendly reports of automatic drug-dispensing machine (“ADM”) data indicating potential drug diversion.
- e. Replacing Bluebell carts in all MGH main campus operating rooms with ADMs; having a timed password-reset for all ADMs (every 90 days); and implementing a biometric identification system (fingerprints) on all ADMs .
- f. Permitting only pharmacists and directly supervised nationally certified pharmacy technicians to have access to the pharmacy vault.
- g. Permitting only authorized MGH pharmacy or IT employees to have access to the ADM server.
- h. Requiring the MGH Department of Pharmacy to conduct daily reviews of ADM reports, including but not limited to instances where more than a certain number of pills were dispensed at one time for one patient (“greater than”

reports), destock verifications, null transactions, medication overrides, and discrepancies.

- i. Requiring the MGH Department of Pharmacy to conduct daily operating room post-case reconciliation (“PCR”) of controlled substances dispensed, used, or wasted, and, if any discrepancy is not resolved within 72 hours, to report the discrepancy to the Drug Diversion Compliance Officer.
- j. Requiring at least one nursing leader per clinical area: (i) to conduct weekly reviews of all controlled substance surveillance software anomalous usage reports for the ADMs in that clinical area; and (ii) to conduct daily reviews (Monday through Friday) of controlled substance surveillance software reports of controlled substances dispensed from the ADMs in that clinical area.
- k. Requiring clinical nursing supervisors to review “greater than” ADM reports on Saturdays, Sundays, and holidays.
- l. Requiring Associate Chief Nurses to conduct monthly compliance checks on their nursing leader direct reports.
- m. Requiring trend and pattern reports to be reviewed quarterly by the Drug Diversion Team.

- 5. MGH will take the following corrective actions in addition to the Enhanced

Controls:

- a. MGH will hire external auditors to conduct unannounced audits at all MGH facilities with active DEA registrations (including all pharmacies and ADMs)

of five Schedule II-V controlled substances randomly chosen by the auditors.

The audits will be conducted at:

- i. 100% of MGH's DEA-registered facilities during the first 12 months following the effective date of this CAP;
- ii. 50% of MGH's DEA-registered facilities between months 13 and 24; and
- iii. 25% of MGH's DEA-registered facilities between months 25 and 36.

Each audit report will be reviewed and signed by the Pharmacist in Charge or the registrant's DEA-designated person. MGH will have 30 days to cure any deficiencies or resolve any discrepancies, and its efforts to cure will be documented in the audit report. If the auditors find any material discrepancies or other material issues (*e.g.*, diversion, missing records, significant losses), MGH will send the audit report to DEA within five business days after the end of the 30-day cure period. MGH will maintain the audit records, and make them available for review by the DEA upon request, for two years after this CAP expires.

- b. During each year of this CAP, MGH will conduct a self-evaluation of all of its DEA-registered facilities to review compliance with all requirements of the Act, the regulations issued under the Act, and this CAP. At the completion of each evaluation, the Pharmacist in Charge or the DEA-designated person at the registrant will certify that he/she has completed the evaluation and document any corrective action to be taken. MGH will retain the letters of

certification, and make them available to the DEA upon request, for two years following the expiration of this CAP.

- c. MGH will maintain all ADM data for two years after the data is created.

MGH will maintain the data in a readily retrievable manner and produce it to the DEA upon request.

- d. MGH will maintain reports of disciplinary action taken against employees found to have lost a significant quantity of controlled substances, or found to have stolen or otherwise diverted controlled substances. To the extent authorized by state or federal privacy laws and regulations, MGH will maintain the reports in an easily accessible manner and produce them to the DEA upon request.

- e. MGH will create and enforce a written policy of progressive discipline applicable to all employees with access to controlled substances.

- f. MGH will promptly investigate all thefts, significant losses, and other potential diversion of controlled substances. MGH will promptly report all such thefts, significant losses, and other diversions to DEA. DEA is aware that MGH has additional reporting duties to licensure boards, and all other relevant agencies (*e.g.*, the Drug Control Program of the Massachusetts Department of Public Health).

- g. If MGH makes a report to an agency that any of its employees has lost or stolen controlled substances, MGH will promptly send a copy of the report to the DEA. If MGH makes a report to an agency that any of its employees has abused or mishandled controlled substances (without a report of loss or theft),

MGH will promptly notify DEA that a report has been made, including the name of the agency and the date of the report.

- h. MGH will promptly notify the DEA when a member of the Drug Diversion team, as identified above in paragraph 4(b), becomes aware that any MGH employee has been arrested or charged by law enforcement on any charges related to theft or diversion of controlled substances.

6. MGH will complete biennial inventories of all of its DEA-registered facilities using physical counts (including counts of all ADMs), witnessed by two individuals.

7. MGH will comply at all times with the Act and the regulations issued thereunder. To the extent that any requirements in the Act or regulations are greater than those imposed by this CAP, the stricter requirements will apply.

8. Each Party and signatory to this CAP represents that it/he/she freely and voluntarily enters into this CAP without any degree of duress or compulsion.

9. This CAP is intended for the benefit of the Parties only; it does not create any rights or benefits for third parties.

10. This CAP is governed by the laws of the United States. The exclusive jurisdiction and venue for any dispute relating to this CAP is the United States District Court for the District of Massachusetts. This CAP shall be deemed to have been drafted by both Parties and shall not, therefore, be construed against either Party in any subsequent dispute.

11. This CAP and the Settlement Agreement constitute the complete agreement between the DEA and MGH relating to the matters addressed herein. This CAP may be amended only by a writing signed by both DEA and MGH.

12. The undersigned signatories represent and warrant that they are fully authorized to execute this CAP on behalf of the parties.

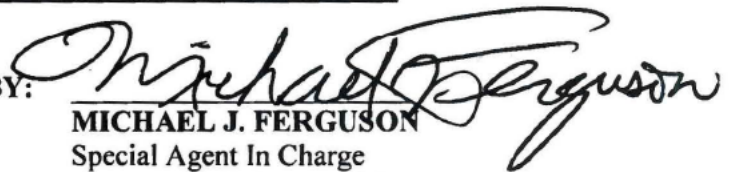
13. This CAP may be executed in two counterparts, each of which constitutes an original and both of which constitute one and the same agreement.

14. This CAP is binding on MGH's successors, transferees, and assigns.


THE U.S. DRUG ENFORCEMENT ADMINISTRATION

DATED: 9/28/15

BY:



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MASSACHUSETTS GENERAL HOSPITAL

DATED: _____

BY:

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MASSACHUSETTS GENERAL HOSPITAL

DATED: 9/28/15

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